COVID-19, IP and access:
will the current system of medical innovation and access to medicines meet global expectations?

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Abstract

The COVID-19 pandemic has exposed the fundamental flaws in the current system of medical innovation and access to medicines, which require urgent attention from the global community. This is prompted by the experience of the past decades, which has proven that this system was ineffective in securing adequate access to medicines for all. The understanding of the deficiencies of the existing system is crucial today, as it may help to design effective approaches for improving access. This article will also consider mechanisms that may be implemented by governments for the protection of public health. These include short-term mechanisms, such as compulsory licensing and government use, as well as the long-term design of a new innovation model, including state-coordinated research of medicines and open innovation. The current system should be reconsidered to ensure the prompt development of COVID-19 therapy accessible to everyone and full preparedness for the pandemics of the future.

Key words: COVID-19, patents, access to medicines, affordable medicines, compulsory licensing, open innovation

Introduction

COVID-19 has brought multiple unprecedented critical challenges to the modern international community. It has severely shaken politics, the economy, environment and, most importantly,

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healthcare. While the world readjusts to the new reality under confusing statistics, lockdowns and social distancing, the global race to develop effective new vaccines and treatment has started.[1] Often overlooked, intellectual property ('IP') is ever-present, adding man-made obstacles to challenging scenarios, such as the extraordinary case of the COVID-19 pandemic. Precious time and resources are currently ill-spent in IP negotiations, and the non-transparent nature of IP-related agreements may pose significant barriers to timely, affordable, and equitable access worldwide. More fundamentally, existing IP practices have already slowed down the reaction speed for the present pandemic and continue to hamper efforts in implementing global preparedness for future pandemics (Hoen, 2020a; Boseley, 2020).

COVID-19 has intensified the traditional debate on IP and access to medicines (Cueni, 2020; Hoen, 2020b). This time, however, in addition to the conventional struggle between patent rights and access to affordable medicines, a new dimension has been brought to this debate. There is a significant concern that the existing manufacturing capacities may become a barrier to access once the vaccines and treatment are developed (IFPMA, 2020a). This is because these medicines will need to be promptly produced and distributed to billions of people worldwide. While pharmaceutical companies are racing to increase their manufacturing capacity (AstraZeneca, 2020a; Hargreaves, 2020; Johnson & Johnson, 2020), this may not be enough for adequate allocation. As a result, some countries, most certainly wealthier western countries, will be the first to access these medicines, leaving others behind (Khamsi, 2020). This was the case during the 2009 H1N1 influenza pandemic, when developed countries placed large advance orders and bought virtually all the output the vaccine companies could manufacture (Brown, 2009; Whalen, 2009; Fidler, 2010). Developing countries had to wait to access these medicines. Nothing was learned from the past. We are currently observing that wealthy countries, including the US, UK and the EU, are placing advance orders at risk for millions of doses of vaccines, prioritising the immunisation of their own citizens. This casts doubt about whether other countries will be able to access any vaccines in time (Cheng and Larson, 2020; Milne and Crow, 2020). This vaccine (Rutschman, 2020) and treatment nationalism (Dutfield, 2020a) may have significant negative effect on public health,[2] because no country will be truly protected from COVID-19 until virtually the entire world is (Peiris and Leung, 2020).

However, the insufficient manufacturing capacities may not be the main problem for access to COVID-19 medicines. There is a fear that IP rights, and patents in particular, may pose a serious risk for the swift development of the COVID-19 vaccines and treatment, as well as the timely and affordable access to such medicines (UNITAID, 2020; Morten and Moss, 2020; Prabhala and Hoen, 2020; The Public Citizen, 2020). These fears are not without merit. For several decades, the problem of access to medicines has been a topic of heated debate at the international level (WTO, WIPO, WHO, 2020; High-Level Panel on Access to Medicine, 2016). The central point has been the tension between, on the one

hand, the exclusive rights stemming from patents and other IP rights that protect medicines and allow pharmaceutical companies to set prices, and, on the other hand, the problem of access to these medicines because of excessive prices.

The aim of this article, therefore, is to expose the fundamental flaws of the current system of pharmaceutical innovation that affect the accessibility of medicines for millions of people. The understanding of these flaws is crucial in the time of the COVID-19 pandemic, as it may help to design effective approaches for improving access. The article argues that in its current state this system is not able to adequately combat pandemics, as well as providing affordable and equitable access to all. In particular, it will explain the proprietary nature of the current system based on strong IP protection and the effect it has on access to medicines. It will then consider mechanisms that may be utilised by governments for the protection of public health at the national and global level. The short-term mechanisms, discussed in this article, such as compulsory licensing and government use, will facilitate better access to patent-protected COVID-19 medicines during this pandemic. The long-term mechanisms of designing a new innovation model, such as state-coordinated research and production of medicines and open innovation, will improve the effectiveness and speed of innovation in this field, leading to an enhanced access to medicines and better preparedness for the pandemics of the future.

1. The current system of pharmaceutical innovation: the proprietary model based on strong patent protection

While patents often lead to unaffordably high drug prices (IMAK, 2018), pharmaceutical companies claim that they need strong patent protection to secure their investments in R&D (European Commission, 2009; IFPMA, 2020b). Therefore, the current legal framework has developed around the model of proprietary research conducted by private pharmaceutical companies, the outcomes of which are typically protected by multiple patents (IMAK, 2018). Such proprietary research has several negative consequences. First, it can lead to a waste of significant time and resources due to duplicative research activities by numerous pharmaceutical companies and the fragmentation of knowledge. Second, these companies typically seek to obtain the broadest and strongest patent protection for the results of their research to achieve market exclusivity, which allows them to set the price of their products. In turn, this often leads to problems of accessing these products due to high prices.

However, the proprietary system of pharmaceutical innovation as we know it today has taken shape fairly recently. In the past, countries were free to develop their national IP-related policies to combat high prices and facilitate access to medicines in accordance with their local needs. Many countries

denied patent protection on medicines or provided only limited protection to the process of their manufacture. Such an approach was based on the fear that patents would create monopolies over such an essential product as medicines (Ho, 2015; Pila, 2009). This, however, changed in 1995 when the WTO Agreement on Trade-Related Aspects of IP Rights ('TRIPS') came into force, which obliged all WTO members to provide patent protection to all types of technologies, including medicines (Abud Sittler *et al,* 2015). These new global rules, coupled with bilateral treaties that strengthen the protection even further (Musungu, 2004), and patent-related strategies by pharmaceutical companies directed at 'evergreening' their market monopoly (Gurgula, 2020), resulted in many countries not being able to provide sufficient access to essential medicines for their populations. As was stated in the Report prepared by the UN High-Level Panel on Access to Medicines in 2016, diseases such as HIV, which have become manageable chronic conditions in developed countries, continue to kill millions of people in low- and middle-income countries because of the unaffordably high prices of patented medicines (High-Level Panel on Access to Medicine, 2016).

Moreover, developed countries are also increasingly suffering from high drug prices, which put significant pressure on national healthcare budgets, forcing governments to reconsider their policies in this field. For example, in 2019 the US FDA approved Zolgensma, a gene therapy developed by Novartis for spinal muscular atrophy, the leading genetic cause of death in infants. The price of the one-time treatment has been set by Novartis at a record $2.125 million, triggering debates about the escalating costs of prescription drugs and access to them (Nat Biotechnol 2019). The 'skyrocketing' prices of patented medicines in the US have prompted an investigation by the House Committee on Oversight and Reform (The US House Committee on Oversight and Reform, 2020a), which has recently held hearings with top executives of major drug companies to examine their pricing practices for some of the costliest drugs in the United States (The US House Committee on Oversight and Reform, 2020b).

Realising the deficiencies of the current system, various calls from governments, international organisations, civil society and academics have been put forward aiming at controlling prices, facilitating access and stimulating genuine innovation (High-Level Panel on Access to Medicine, 2016). Despite this no tangible changes in the operation of this system have occurred.

2. Is the current system of pharmaceutical innovation fit to fight the COVID-19 global pandemic?

While the problem of access to medicines that stems from the current system is not new, what is disturbing today is that we are relying on this failed system to provide the solution to the global coronavirus pandemic by developing breakthrough medicines and providing affordable and equal

access worldwide. Appreciating that the most pragmatic way to combat the pandemic is through collaboration and data sharing, the WHO has launched an unprecedented cooperation between countries and various institutions. It calls for action by key stakeholders and the global community 'to voluntarily pool knowledge, IP and data necessary for COVID-19' (WHO, 2020a). WHO director-general Tedros Adhanom Ghebreyesus noted that '[b]ased on strong science and open collaboration, this information-sharing platform will help provide equitable access to life-saving technologies around the world' (WHO, 2020b). Other initiatives for voluntarily sharing the relevant knowledge, IP and data to enable widescale and worldwide production, distribution and use of such technologies and necessary raw materials include the Technology Access Partnership hosted by the UN Technology Bank (TAP, 2020) and the Open COVID Pledge Initiative (Open COVID Pledge, 2020). While such initiatives to share IP knowledge and patent pools are not new, their experience in facilitating access to medicines may be invaluable in accelerating the development of COVID-19 vaccines and treatment (Medicines Patent Pool, 2020). Even the European Commission is temporarily adjusting its views, understanding that 'this extraordinary situation may trigger the need for companies to cooperate in order to ensure the supply and fair distribution of scarce products to all consumers', and therefore it will 'not actively intervene against necessary and temporary measures put in place in order to avoid a shortage of supply.' (European Commission, 2020). However, while impressive as to the scale of their potential, all these initiatives are lacking the most important key player – the pharmaceutical industry (Mancini and Peel, 2020; Medicines Law & Policy, 2020a; IFPMA, 2020a). Without its active participation in these and other initiatives the chances for success of such endeavours are rather slim.

Unfortunately, it seems that pharmaceutical companies are reluctant to engage in these initiatives, as this would mean sharing their IP (Ren, 2020). In the recent briefing organised by the International Federation of Pharmaceutical Manufacturers and Associations, chief executives from Pfizer, GlaxoSmithKline, AstraZeneca and J&J, which are all currently in the race to develop COVID-19 vaccines and treatment, were unsupportive of the WHO initiative of sharing IP (IFPMA, 2020a; Mancini and Peel, 2020; Lovett, 2020). As a result, this pandemic has exposed our pervasive dependence on private pharmaceutical companies. While several pharmaceutical companies have declared that they will make their vaccines available at cost for the duration of the COVID-19 pandemic (AstraZeneca, 2020b; Scheuber, 2020; Wu, 2020; Peel *at el.*, 2020), we must not forget that the pharmaceutical industry is a profit-oriented business. Moreover, it is not designed to operate in such extraordinary circumstances. Pharmaceutical companies are responding to the crisis by doing what they have been optimising to do in the recent years: a competitive race of proprietary research in parallel to each other, teaming up with small tech companies or universities to boost their chances. While in normal circumstances, this rivalry could be beneficial by providing different options to tackle a disease, the current circumstances and timelines are not ordinary. Therefore, the normal mechanisms of competition should not control the development of the solutions that are literally expected to save the world. Despite

numerous claims being made by pharmaceutical companies that it is not 'business as usual' anymore (IFPMA, 2020c), the reality is different. COVID-19 has not altered the operation of the industry. Pharmaceutical companies are engaging in proprietary research and generating their proprietary data, the outcomes of which will still be protected by IP rights. This results in an enormous expenditure of resources and time, with unpredictable outcomes both in terms of efficacy/safety of the researched medicines (Mallapaty and Ledford, 2020), as well as the price it will cost for society.[3]

This reveals two fundamental flaws in the current system. First, a proprietary/competitive model slows down the success as it prevents researchers from working together in tackling the virus in contrast to a more open and collaborative model by pooling resources and efforts and leading to faster and more efficacious outcomes. Second, any resulting therapy developed by pharmaceutical companies will be protected by patents, allowing them to control the production and price of, as well as access to the vaccines and treatment (Gilead, 2020).

3. Short-term measures to ensure affordable and equitable access to COVID-19 medicines using available mechanisms: compulsory licensing and government use

Pharmaceutical companies continue to actively patent the results of their research (Koons, 2020; Prabhala and Hoen, 2020), and, therefore, the effect of such practices on access to COVID-19 therapy should be considered. As discussed above, patents bestow exclusive rights upon their owners. This means that the patent holder has the right to prevent others from using his or her invention, and thus control the manufacture and distribution of such products, including their prices (*Correa, 2020*). As a result, patents may preclude the possibility of purchasing medicines at low prices or in required quantities because, for example, they are priced at a level that is not affordable for patients or government bodies, or the patent holder is not able to supply a sufficient amount of such medicines (ibid). In these circumstances, patent holders have the right to prevent supplies from alternative sources (ibid). This is particularly dangerous today as the exclusive patent rights to COVID-19 vaccines and medicines may restrict or even block access to such a therapy. This danger is especially significant for developing countries that may not be able to procure a sufficient amount of patent-protected COVID-19 vaccines and treatment due to high prices.

While patents provide exclusive rights, the exercise of such rights by the patent holder may be limited in view of public interests, including the protection of public health (ibid). International laws contain specific mechanisms, such as 'compulsory licences' and 'government use for non-commercial purposes', which allow restricting the exercise of exclusive rights under the patent. These mechanisms

can be found in Article 31 of the TRIPS Agreement. Moreover, in 2001, the Doha Declaration on the TRIPS Agreement and Public Health[4] confirmed that the granting of compulsory licences was one of the flexibilities under the TRIPS Agreement, which all WTO members have the right to use if necessary.[5] These mechanisms have been implemented in the majority of jurisdictions worldwide and may be relied upon to address public health needs (ibid).

A compulsory licence is an authorisation granted by a state authority that allows the person who receives it to use the invention without the agreement of the patent holder (Medicines Law & Policy, 2020b). While most countries have integrated the regime of compulsory licences into their IP legislation, the grounds for granting such licences may vary (European Patent Academy, 2018). The typical grounds include the following: (a) market demand not sufficiently satisfied, (b) exploitation of patent rights violates competition law (e.g. excessive prices), (c) patentees abuse their exclusive rights; (d) public interest (e.g. health, environment, economic development, national security); (e) dependent patents (e.g. technical improvement) (Biadgleng, 2009).

To help governments in securing a sufficient amount of COVID-19 medicines, a special type of compulsory licence can be utilised. This is called 'government use' (Pochart *et al*., 2020),[6] under which the state grants authorisation for its *own use,* meaning that such authorisation is given to a state agency or department, or even to a private entity (Medicines Law & Policy, 2020b). The effectiveness of this mechanism manifests in the fact that the government is not required to send a formal request to the patent holder, it can act *ex officio* to tackle specific public health issues (Correa, 2020). This means that governments will not need to spend time on negotiating a licence, as required by Article 31 TRIPS in relation to a normal compulsory licence, but can grant a government use when it considers it necessary.

While this mechanism was implemented in the TRIPS Agreement as one of the flexibilities to balance strong protection stemming from the exclusive patent rights, it has not been used frequently. Among the relatively small number of government uses, the majority of such authorisations were granted by developing countries that were unable to satisfy the needs of their population in life-saving treatments for such diseases as HIV, Hepatitis C and cancer, due to the high prices charged by the pharmaceutical companies – the patent owners.[7] For example, in 2017, **t**he Government of Malaysia issued a compulsory licence on the Hepatitis C treatment sofosbuvir (Sovaldi) as the price for this medicine was prohibitively high (Treatment Action Group, 2017). Such an infrequent use of this mechanism by developing countries was mainly due to significant political pressure from developed countries (typically the US and EU), which required developing countries to refrain from granting compulsory licences that would affect the interests of multinational pharmaceutical companies under the threat of retaliation (Radhakrishnan and Amin, 2013; Reichman, 2010). This was despite the fact that, as was

noted above, the grant of a government use or compulsory licence was in line with the provisions of the TRIPS Agreement and, therefore, any WTO member has the right to utilise it.

Since the adoption of the TRIPS Agreement in 1995 and before the COVID-19 pandemic, developed countries used this mechanism (both compulsory licensing and government use) only a few times. One of the rare examples is Italy. In 2017, due to the high price of Hepatitis C medicines, the Italian government granted its citizens the right to import more affordable generic versions for their personal use (Hoen *et al*, 2018). Another rare example is Germany, where the court granted a compulsory licence for the HIV drug raltegravir based on public interest (GRUR, 2017). However, this mechanism has attracted closer attention during the COVID-19 pandemic. Some countries have already granted compulsory licences for medicines that can be used in treating COVID-19 patients. For example, on 18 March 2020 Israel's Minister of Health issued a permit to the state allowing the importation of Kaletra (lopinavir 200mg/ritonavir 50mg) for the purpose of medicinal treatment of COVID-19 patients (KEI, 2020). Other countries have been changing their national laws to make this mechanism more efficient. This includes Germany (Hoen, 2020a; Pochart *et al,* 2020).[8] In particular, Section 13 of the German Patent Act ('GPA') enables the federal government to issue orders for the use of an invention to protect public welfare by the government or government-appointed third parties (Fuchs, 2020).[9] To make this mechanism more efficient during the pandemic, on 28 March 2020, the German government passed a 'corona crisis package', which introduced several changes to existing laws (Klopschinski ,2020).[10] It has amended, *inter alia,* the Act on the Prevention and Control of Infectious Diseases in Humans and introduced, among others, Section 5 which provides the Ministry of Health with additional powers to control the epidemic situation, including the authority to order restrictions on patents in accordance with Section 13 GPA (ibid). This can be done in relation to specific products which can be used for public welfare, such as pharmaceuticals, medical devices, laboratory diagnostics, items of personal protective equipment and products for disinfection.[11]

To prevent any delays in accessing COVID-19 therapy governments should utilise all the available mechanisms. With respect to patent-protected therapy, one of the effective tools, as was discussed above, is government use.[12] It is provided by the TRIPS Agreement and can be found in most national patent laws. It is, however, important to review national laws on government use and amend them where necessary to maximise the effectiveness of this mechanism, making sure that there will be no barriers in using it when required. Moreover, governments, especially in developing countries, should not refrain from authorising government use based on their fears of political retaliation from developed countries. Today, both developing and developed countries should use all the tools available to ensure that COVID-19 therapy is accessible to their population in a sufficient amount and at a price they can afford.

4. Long-term measures to ensure affordable and equitable access to medicines globally

While the measures discussed above may provide a solution for affordable access to certain COVID-19 therapeutics in the short term, they will not solve the problem of access in general. Such an unprecedented global pandemic is the result of a global market failure, which needs urgent intervention. To avoid the universal problem with access to COVID-19 medicines, as well as to prepare for the future pandemics, the current system requires drastic changes. There are a number of options for such changes available today. These include, for example, a state-coordinated research and production of medicines to fight pandemics, and the development of a new model of open innovation.

The first approach essentially means that the state should assume the function and responsibility for the preparedness to such health-related risks as pandemics. A comprehensive infrastructure should be set in place, which would cover both the research into and production of medicines needed for health security (Brown, 2010). Therefore, the establishment of new specifically designated research centres to investigate and prepare for new pandemics, and setting up the infrastructures for the development and manufacture of medicines by countries, may help to reduce the risks of new pandemics, as well as securing access to essential medicines when the pandemic ends.

Another option is to create a system of open innovation, in which access to information, data and technologies could be freely achieved. 'While innovation is critical, the usual process of managing innovation does not seem to work anymore' (Chesbrough, 2003). This is the view that Chesbrough expressed almost 20 years ago and it is still valid today. He explained that the old paradigm of innovation was based on the closed model, where companies generate their ideas, develop, build, market and finance them on their own (ibid). One of the implicit rules of this model is 'we should control our IP, so that our competitors don't profit from our ideas' (ibid). He further claimed that this paradigm created a 'virtuous circle', in which companies invested in their R&D, which led to breakthroughs, increasing their profits, which were then reinvested back into their internal R&D (ibid). Since IP was vigorously protected, others could not use it for their own profit (ibid). This paradigm that according to Chesbrough worked for most of the twentieth century has become unsustainable in the twenty-first century (ibid; Dutfield, 2020), and the pharmaceutical industry is a good example. Despite the alleged surge in investments into pharmaceutical R&D, the pipeline of breakthrough medicines is decreasing, with very few truly novel medicines being developed recently (Pammolli *et al,.* 2011; Scannell *et al.,* 2012; Light and Lexchin, 2012; IMAK, 2018). Realising that the closed model of innovation in this field is not viable anymore, pharmaceutical companies have been increasingly turning to external sources of innovation (Schuhmacher *et al.,* 2018). During recent years, pharmaceutical companies have been establishing collaborations with academic centres of excellence, building innovation centres,

creating joint ventures with academic institutions (public-private partnerships), setting precompetitive consortia, or experimenting with crowdsourcing and virtual R&D (ibid).

These new approaches, however, are mainly followed if they fit with companies' traditional, predominantly internal (i.e. closed) R&D models and in research areas that do not affect their major franchises (ibid). Despite the great potential that the open innovation model may bring to society in this field, the pharmaceutical industry has been hesitant to utilise it. One of the main reasons is that this will mean changes to their traditional approaches, as well as because of the fear of losing control over their valuable IP assets. The apogee of this state of affairs is the current pandemic, in which pharmaceutical companies have refused to share their IP with the open innovation pledges discussed above, which would allow an acceleration of the process of developing the COVID-19 therapy. This system based on the closed (or semi-closed) model of innovation that relies on strong IP protection, which has already proven to be ineffective in the past, poses a risk to humanity by preventing researchers from accessing the valuable information related to COVID-19 therapeutics that is currently being generated in hundreds of laboratories worldwide. If employed, the open innovation model would eliminate 'the fragmentation of knowledge that is inherent to the IP-driven pharma industry' (ibid) and would allow a free flow of information, enabling more efficient use of resources and faster development of medicines, including for COVID-19.

Both options have their pros and cons, which need to be carefully assessed prior to their implementation. For example, the establishment of the state infrastructure would allow countries to be better prepared for pandemics in the future without overreliance on the private pharmaceutical business. However, it may lead to inequality of access, since wealthier countries would be in a better position to create such infrastructures, while poor countries will not be able to do this. On the other hand, the open innovation system may help to boost medical research, as access to crucial information will not be restricted by IP rights, thus allowing scientists around the world to share and utilise such data for the benefit of society. This will mean that the system of IP protection would need to be redesigned, so that it would not create a barrier for access. However, as was mentioned above, pharmaceutical companies argue that without the current level of IP protection, they will have no incentives to engage in R&D. Therefore, alternative incentives for pharmaceutical companies may need to be developed in order to attract their interest in this new system. For example, such incentives may be based on performance, with governments collectively setting the bar for what they would purchase and at what price.

Conclusions

While the model for a new system of medical innovation and access is yet to be developed, what is clear today is that the long overdue changes to the current system are inevitable. This pandemic has exposed the fundamental flaws in the existing system which require urgent attention from the global community. This is prompted by the experience of the past several decades, which has proven that this system was ineffective in securing adequate access to medicines for all. It has also exposed our overwhelming dependence on the private pharmaceutical business for protecting global health security. It is paramount that governments utilise all available mechanisms that would ensure swift and equitable access to COVID-19 therapy, including issuing compulsory licenses and authorising government uses where necessary. Moreover, drawing on past experience, we need to fundamentally and urgently rethink the model of medical innovation and access in order to ensure that we are able to find prompt solutions for the development of COVID-19 medicines which will be accessible to everyone, as well as allowing us to be fully prepared for the pandemics of the future. For this, all the stakeholders, including governments, pharmaceutical companies, international non-governmental bodies, non-profit organisations, academics, and public initiatives, must work together to find the most suitable and workable solution that would be beneficial for society.

Notes

1 'Covid-19 Vaccine Tracker' (as of the time of writing 236 vaccines are in development and 38 are in clinical testing, 7 have reached a regulatory decision) <https://www.covid-19vaccinetracker.org/>; 'Covid-19 Treatment And Vaccine Tracker' <https://milken-institute-covid-19-tracker.webflow.io/#vaccines_intro>.

2 WHO Virtual Press conference on 06 August 2020 (According to Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization, '[f]or the world to recover faster it has to recover together. Because it's a globalised world. The economy is intertwined. Part of the world or few countries cannot be a safe haven and recover. They should recover together with the rest of the world'). Available at: https://www.who.int/docs/default-source/coronaviruse/transcripts/who-broll-emergencies-coronavirus-press-conference-06aug2020.pdf?sfvrsn=d9ec783b_2 (accessed 19 December 2020).

3 These consequences of strong patent protection on medicines can be contrasted with the potential benefits and effect of medicines that are not encumbered by numerous patents in fighting the COVID-19 pandemic. A good example is dexamethasone, 'a steroid that has been used since the 1960s to reduce inflammation in a range of conditions, including inflammatory disorders and certain cancers. It has been listed on the WHO Model List of Essential Medicines since 1977 in multiple formulations, and is currently off-patent and affordably available in most countries' ('WHO welcomes preliminary results about dexamethasone use in treating critically ill COVID-19 patients' (16 June 2020) Available at: https://www.who.int/news/item/16-06-2020-who-welcomes-preliminary-results-about-dexamethasone-use-in-treating-critically-ill-covid-19-patients (accessed 19 December 2020)). The initial clinical trial results revealed by the RECOVERY (Randomised Evaluation of COVID-19 Therapy) led by the University of Oxford has shown that dexamethasone can reduce mortality in patients who are critically ill with COVID-19. Available at: https://www.recoverytrial.net/ (accessed 19 December 2020).

4 WT/MIN(01)/DEC/W/2, 14 November 2001. Available at: www.wto.org (accessed 19 December 2020).

5 Doha Declaration on the TRIPS Agreement and Public Health. Sub-paragraph 5 (b) 'Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: … b. Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.'

[6] E.g. UK law contains such concept as 'crown use'. See e.g. Section 55 of the Patents Act 1977.

[7] Examples of compulsory licensing, including public non-commercial use, can be found in the TRIPS Flexibilities Database that provides worldwide information on the instances when authorities have invoked, planned to invoke, or have been asked to invoke a TRIPS flexibility for public health reasons, in particular to assure access to medicines. See Medicines Law & Policy. The TRIPS Flexibilities Database available at: http://tripsflexibilities.medicineslawandpolicy.org (accessed 19 December 2020); see also the WIPO Database on Flexibilities in the Intellectual Property System, which includes references to all legislations on TRIPS flexibilities, including on compulsory licensing. Available at: https://www.wipo.int/ip-development/en/agenda/flexibilities/database.html (accessed 19 December 2020).

[8] Similar measures have also been implemented in France by the emergency law n° 2020-290 of 23 March 2020 to deal with the COVID-19 epidemic, which introduced a new article L.3131-15 in the public health code authorising the Prime Minister to undertake certain measure for the purpose of guaranteeing public health, including granting government use (see Pochart *et al.,* 2020).

[9] Section 13 GPA '(1) The patent shall have no effect in a case where the Federal Government orders that the invention is to be used in the interest of public welfare. Further, it shall not extend to a use of the invention which is ordered in the interest of the security of the Federal Republic of Germany by the competent highest federal authority or by a subordinate authority acting on its instructions' (see Fuchs, 2020).

[10] These amendments have been enacted by the Act on the Protection of the Population in Case of an Epidemic Situation of National Significance, which entered into force on 28 March 2020.

[11] Section 5 of the Act on the Prevention and Control of Infectious Diseases in Humans.

[12] It is worth mentioning that TRIPS regulates compulsory licensing and government use in relation to patents. Therefore, the application of such mechanisms may need further examination in relation to vaccines, the protection of which would typically also entail trade secrets.